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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,867	06/05/2006	Michael Horstmann	RO4244US (#90568)	3928
28672 7590 04/15/2009 D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114			EXAMINER BLIZZARD, CHRISTOPHER JAMES	
			ART UNIT 3771	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/581,867	Applicant(s) HORSTMANN ET AL.	
	Examiner CHRISTOPHER BLIZZARD	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/5/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 June 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to amendment filed 6/5/06. As directed by the amendment, claims 1-23 were amended, claims 24-30 were added. Thus, claims 1-30 are presently pending in this application.

Drawings

2. The drawings are objected to because they contain faded and blurred lines, difficult to read reference numbers and difficult to interpret cross hatching. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

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3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 1-30, the phrase “at least one of said at least one additional preparation containing at least one” found in claim 1 is a range within a range, and thus renders the claims indefinite.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 5, 10, 12, 17, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Honeycutt (4,765,348).

8. Regarding claims 1, 2, 5, 10, 12, 17, 22 and 23, Honeycutt discloses a device for administration of nicotine to the human body by inhalation (column 1, lines 37-45) for the purpose of being a non-combustible simulated cigarette (column 1, 8-10), wherein the device comprises a first preparation (18) containing a free base of nicotine (column 1, lines 45-46) contained in a polytetrafluoroethylene matrix (column 3, lines 11-18), and a second preparation

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(20) containing a volatile acid (column 1, lines 46-52), such as acetic acid (column 2, line 39) which is separated from the first preparation (18) by an impermeable partition (24) (column 2, lines 48-49). The device contains a first air inlet, located to the right of section 18 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #18 in figure 3, a second air inlet, located to the right of section 20 in figure 3, directing an inhaled airstream into an oblong air supply channel, around #20 in figure 3, a common flow path (22) where the two airstreams from the separate sections combine simultaneously due to inhalation and an outlet aperture (16) where the common flow path leads to (column 2, lines 60-69).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 3, 4, 9, 24, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348) in view of Ray (4,284,089).

11. Regarding claims 3, 4, 9, 24, 25 and 27 Honeycutt does not disclose the preparations containing a solvent suitable for inhalation. Ray teaches a preparation containing water as a solvent as well as menthol dissolved in ethanol as a flavoring (column 4, lines 23-28; column 7, lines 14-22). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was

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made to provide the inhaler of Honeycutt with solvents as taught by Ray in order to provide the advantages of adjusting the humidity of vapors released and providing flavor to the vapors.

12. Claims 6, 7, 8, 14, 26, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348)

13. Regarding claim 6, Honeycutt discloses the chemical balance between volatilized nicotine and acid can be controlled (column 3, lines 1-10), but does not disclose the exact ratio of the chemical balance. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made that during inhalation a ratio of equimolar quantities of the nicotine and acid could be released in order to provide the advantage of giving the vapor a neutral pH.

14. Regarding claims 7, 8, 14, 26 and 30, Honeycutt discloses the claimed invention except for the inspiration duration, velocity, nicotine dose, particle size, and negative pressure differential. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device with appropriate size elements to create airflows and chemical balances necessary to operate the device successfully (column 3, lines 1-10), since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

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15. Regarding claim 28 and 29, Honeycutt discloses the device having an impermeable part (24) (column 2, lines 48-49) as well as discloses that the device can be made of any material (column 2, lines 11-13), but does not disclose a definite composition of the whole device. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the entire device out of the impermeable material of impermeable partition (24) and for this material to be a polyester material coated with a copolymer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

16. Claims 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348) in view of Turner (5,400,808).

17. Regarding claim 29, Honeycutt does not disclose the material which is impermeable. Turner teaches a nicotine impermeable container constructed of aluminum foil coated with a copolymer of acrylonitrile and methyl acrylate (column 2, lines 36-41). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt a material as taught by Turner in order to provide the advantage a longer shelf life of the contents of the inhaler.

18. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348) in view of Ferre (726,037).

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19. Regarding claim 13, Honeycutt does not disclose a peelable protective layer to form compartments containing the active agent and acid protecting them from ambient air. Ferre teaches an inhaler with separate impermeable (lines 53-54) compartments (a, c) that have orifices (f) that can be opened or closed (line 70). Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the inhaler of Honeycutt with a sealable compartments as taught by Ferre, and for the compartments to be sealable with a peelable layer in order to provide the advantage of a longer shelf life of the contents of the compartments as well as an inexpensive disposable sealing means.

20. Claims 15, 16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Honeycutt (4,765,348) in view of Kallstrand (5,660,169).

21. Regarding claims 15, 16, and 18-21, Honeycutt discloses the claimed invention except for a part formed by deep-drawing. Kallstrand discloses an inhaler device with an upper (1) and bottom part (2), containing a compartment with a peelable seal (figs. 3a-c), formed by deep-drawing (column 2, lines 11-14). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the inhaler of Honeycutt with deep-drawn components as taught by Kallstrand in order to provide the advantage of an inexpensive way to manufacture the device.

Conclusion

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Rose (6,595,209) an inhaler with a porous matrix element,

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Horstmann (6,207,183) a surface for a preparation of pharmaceutical product, and Hurka (4,841,964) an inhaler formed by deep drawing.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER BLIZZARD whose telephone number is (571)270-7138. The examiner can normally be reached on Monday thru Friday, 9:00AM -5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571)2724835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CHRISTOPHER BLIZZARD/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner
Art Unit 3771

